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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/276,868 | 03/26/1999 | MICHAEL SIMONS | BIS-043 | 2716 |

7590 09/20/2005

DAVID PRASHKER PC
PO BOX 5387
MAGNOLIA, MA 01930

EXAMINER

KAM, CHIH MIN

ART UNIT PAPER NUMBER

1656

DATE MAILED: 09/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/276,868 | SIMONS ET AL. | |
| | Examiner | Art Unit | |
| | Chih-Min Kam | 1656 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 July 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11 and 13-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) 11 and 13-15 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

(Handwritten mark)

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DETAILED ACTION

Status of the Claims

1. Claims 11 and 13-15 are pending.

Applicants' amendment filed July 5, 2005 is acknowledged, and applicant's response has been fully considered. Claims 11 and 15 have been amended, and claim 12 has been cancelled, thus claims 11 and 13-15 are examined.

Withdrawn Claim Rejections - 35 USC § 102

2. The previous rejection of claims 11-15, under 35 U.S.C. 102(b) as anticipated by Blecha *et al.* (WO 96-32129), is withdrawn in view of applicants' amendment to the claim, applicant's cancellation of the claim and applicant's response at pages 8-25 in the amendment filed July 5, 2005.
3. The previous rejection of claims 11-15, under 35 U.S.C. 102(a) as anticipated by Chan *et al.* (J. Biol. Chem. 273, 28978-28985), is withdrawn in view of applicants' amendment to the claim, applicant's cancellation of the claim and applicant's response at pages 25-30 in the amendment filed July 5, 2005.

New Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 11 and 13-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the

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relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 11 and 13-15 are directed to a PR-39 derived oligopeptide family whose members individually are operative and functional to cause a selective inhibition of proteasome-mediated degradation in-situ after introduction intracellularly to a viable cell, each member of said PR-39 derived oligopeptide family being a pharmacologically active oligopeptide which is less than 14 or 12 amino acid residues in length, whose N-terminal amino acid residue sequence begins with Arg-Arg-Arg, which is an analog of the amino acid sequence of native PR-39 peptide, which selectively alters the proteolytic degradation activity of proteasomes, which is selectively interacts in-situ with at least the $\alpha 7$ subunit of proteasomes, and which is selectively inhibits proteolytic degradation mediated by the proteasomes against at least one peptide of I κ B α and hypoxia-inducing factor-1 α . The specification indicates a member of PR-39 derived oligopeptide family is less than 39 amino acid residues, preferably is less than 20 residues (page 24, lines 12 –13), and further discloses the amino acid sequences of specific members such as PR-15, PR-11 and PR-8 (the N-terminal fragments of PR-39; page 25), it does not describe any particular structure to function/activity relationship in the disclosed species, the PR-39 oligopeptides which are less than 14 or 12 amino acid residues. The lack of description of the correlation of structure to function/activity, and lack of representative species for the claimed peptide, one skilled in the art would not know how to identify a functional peptide. Thus, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise terms that a skilled artisan would not recognize applicants were in possession of the claimed invention.

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Conclusion

5. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Chih-Min Kam, Ph. D. *CMK*
Patent Examiner

CMK

September 12, 2005


KATHLEEN M. KERR, PH.D.
SUPERVISORY PATENT EXAMINER